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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,117	03/09/2000	William Scott Caldwell	627-311CT	2879

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EXAMINER
BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
1624	19

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/522,117	CALDWELL ET AL.	
	Examin r	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' response, which included a declaration from Dr. William Caldwell, filed on 6/14/2002, is made of record.

Claims 21-27 are pending.

In view of applicants' response the following apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caldwell et al. US 5,861,423 for reasons of record.

Applicants' argument to overcome this rejection with a declaration from Dr. Caldwell is not persuasive.

The Declaration by Dr. Caldwell is insufficient to overcome the above rejections because the results provided are not commensurate in scope with the claims. The instant claims are drawn to compounds having a α-methyl substituent on the carbon atom of the side chain to which N-methylnitrogen is attached. Both cis and trans as well as R and S isomers are embraced. However, all of the data provided in Table 5 and the discussion of unexpected superiority is with respect to compounds having a α-methyl substituent on the carbon atom, which is next to the amino group especially the trans, R and S compounds. Even among the compounds having α-methyl, the superiority is

established in favor of S-isomers, see the discussion in paragraph 11 on page 5. Particularly, from the results provided in Table 5, no superiority is observed for the R-isomer (compound 2) as compared to the unsubstituted compound (compound 1) in terms of the activity ratio. It is also true when comparing the activity ratio data provided in Table 5, no significant difference has been observed between the α-methyl R-isomer (compound 2) compared to the unsubstituted compound (compound 1) both of which appear to be better than compound 3. Further, applicant's conclusion is also with respect to the superiority of α-methyl compounds and particularly towards the S enantiomers (see paragraph 11 in page 5), therefore, the comparative data is not found to be commensurate in scope with the claims. There is no theory provided detailing how to extrapolate the data of the α-methyl S-isomers to other compounds encompassed by the claimed genus, i.e., compounds wherein the α-methyl group R and S with both cis and trans geometrical thereof. Such comparative data and/or explanation would be necessary to establish that the provided evidence is of probative value. See MPEP 716.02(d).

See Ex parte Gelles 22 USPQ 2nd 1318. Note Gelles, especially the following quote: " The evidence relied upon also should be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter " as a class" relative to prior art subject matter."

See also MPEP 716.02(e), which states:

Showing unexpected results over one of two equally close prior art references will not rebut prima facie obviousness unless the teachings of the prior art references

are sufficiently similar to each other that the testing of one showing unexpected results would provide the same information as to the other. In re Johnson, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984).

For all the above reasons, the rejections under 35 USC 103(a) are maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending

Application No. 08/631,761. Although the conflicting claims are not identical, they are not patentably distinct from each other because subject matter embraced herein is also embraced in the copending application 08/631,761.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No.09/570,226 Although the conflicting claims are not identical, they are not patentably distinct from each other because subject matter embraced herein is also embraced in the copending application 09/570,226

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Note all these rejections were same as made in the previous office action and are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

References cited in the Information Disclosure Statement (paper # 12) are made of record except for except for the Partial European Search Report, which is not a publication per se and thus is not properly cited as such in the IDS. See MPEP 2205.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Balasubramanian
Venkataraman Balasubramanian

9/3/2002